PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 34323WOP00	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/000450	International Filing Date *(day/month/year)* 16 April 2003	Priority Date *(day/month/year)* 16 April 2002

International Patent Classification (IPC) or national classification and IPC

Int. Cl. [7] G01N 1/10, 30/72, 33/487

Applicant

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1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of the report
10 November 2003	20 July 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **LARS KOCH** Telephone No. (02) 6283 2551

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU2003/000450

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

The international application does not complied with the requirements of unity of invention because it does not relate to one invention or a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are two inventions:

1. Claims 1-16 are directed to a sample collection device including an inert collection matrix attached to a support. Claim 37 is a method claim for collecting a sample by using the sample collecting device as stated above. It is considered that a sample collecting device attached to a support or a method of using the aforesaid comprises a first "special technical feature". The dependent claims of claim 1 add additional features that from the description appear to be mere embodiments.

2. Claims 17-36 are directed to a method of detecting simultaneously a plurality of elements in a fluid sample adsorbed/absorbed onto or into an inert collection matrix or supported on an impermeable substrate comprising:

(i) exposing the sample to high energy radiation capable of ionising at least a portion of the sample, and

(ii) detecting plurality of elements in the ionised portion of the sample by mass spectrometry.

It is considered that exposing the sample to high energy radiation capable of ionising at least a portion of the sample prior to the step of detecting a plurality of elements in the ionised portion of the sample by mass spectrometry comprises a second "special technical feature".

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims **3, 5, 7-9, 11-13, 15, 16, 18-25, 27-36**	**YES**
	Claims **1, 2, 4, 6, 10, 14, 17, 26, 37**	**NO**
Inventive step (IS)	Claims **21, 22**	**YES**
	Claims **1-20, 23-37**	**NO**
Industrial applicability (IA)	Claims **1-37**	**YES**
	Claims	**NO**

2. Citations and explanations (Rule 70.7)

Citations:

(a) US 5 179 005

(b) DE 20 118 772

(c) US 6124 012

(d) EP 852 336

(e) EP 345 781

(f) EP 715 337

(g) WO 94/28418

(h) EP 738 000

(i) WO 96/03768

(j) WO 01/94910

(k) US 2001/013579

Novelty and Inventive step: claims 1 and 14

The invention of claims 1 and 14 is directed to a sample collection device including a collection matrix layer is capable of adsorbing or absorbing a fluid sample and either affixed to an area of solid support or sandwiched between two support layers. Such features are readily found in one or more of citation documents (a), (b), (c), (d) or (e) respectively.

Similarly claims 2, 4, 6 and 10 are not considered novel as they are clearly disclosed in one or more of the above citations (eg claim 10 - a lancet, is disclosed in citation (b)).

Claims 3, 5, 7-9, 11-13 and 15-16 are considered to be mere embodiments which are common general knowledge to a skilled addressee and as such not considered or inventive. For example having a fluid sample selected from body fluids, oils and water or more specifically blood, urine or sweat (as per claims 15, 16) is considered a common practice in the art and as such lacking in an inventive step.

Continued in Supplemental Sheet

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box IV

Consequently the claims do not share a common feature which constitutes "a special technical feature" within the meaning of PCT Rule 13.2, since it makes no contribution over the prior art. Since there exists no other common feature which can be considered as a special technical feature within the meaning of PCT Rule 13.2, no technical relationship within the meaning of PCT Rule 13 between the different inventions can be seen. Consequently it appears that a posteriori, the claims do not satisfy the requirement of unity of invention.

However as all inventions were searched, this opinion is based on all claims as presently filed.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

Furthermore the invention of claim 1 is not considered inventive in the light of the common general knowledge in the art. Commercially available inert matrices are well known, as indicated in the present specification in *Example 2*, page 10 for example. It is considered obvious and part of the common general knowledge for a skilled addressee to affix a commercial available inert matrices to a generic solid support such a piece of plastic or cardboard or the like for the purpose of creating a sample collection device. For similar reasons claims 2 -9 are considered to lack an inventive step.

Novelty and Inventive step: claims 17, 18, 19, 20, 21 and 22.

Throughout these claims it is noted that the feature of an inert collection matrix is not considered essential to the invention. This construction is derived from a fair reading of the specification, throughout which there are reference to collecting a sample without the requirement of an inert collection matrix. See for example pages 5, 9 and particularly page 12, which states the collection matrix may simply be omitted and the sample supplied directly to the support material.

The invention of claim 17 defines a method of detecting simultaneously a plurality of elements in a fluid sample adsorbed onto or into an inert collection matrix. The method comprising the steps of exposing the sample to high energy radiation capable of ionising at least a portion of the sample and detecting a plurality of elements in the ionised portion of the sample by mass spectrometry.

In the light of the above construction, this claim is not considered novel when compared with citation (f)-(k). See for example the claims of citation (f), or page 6 of citation (i).

Claim 18, whilst also independent, further adds the feature of quantifying simultaneously a plurality of elements in the sample. This claim is not considered inventive when compared with many of the citations (f)-(k) which clearly disclose exposing the sample to high energy radiation, but do not clearly disclose of quantifying the plurality of elements present. Most of the citations discuss "analysing the sample" or words to that effect. It is considered obvious that quantifying the elements, as a percentage of the total for example, is a common type of analysis undertaken when using mass spectrometers.

Claims 19 and 20 are directed towards a method of quantifying similar to claim 18, with the additional feature of having an internal standard applied to it. This is not considered inventive (for similar reasons to those outlined above) compared to citation (k) (amongst others) at page 1 which clearly described the use of an ionised internal standard in the form of a calibration solution which is also ionised.

Claims 21 and 22 are considered novel and inventive over the material cited in the International Search Report as there is no single citation or obvious combination which clearly disclose a method of quantifying simultaneously a plurality of elements including the steps of exposing a matrix-matched Certified Reference Material to high energy radiation capable of ionising a portion of the CRM and determining the quantity of the plurality of elements in the sample with reference to the CRM as claimed in these claims.

Novelty and Inventive step: claims 23 -36

The invention of these claims appear to be no more than embodiments which are considered to be no more than common general knowledge to a skilled addressee. As such many of these claims are either not novel or inventive in the light of citations (f)-(k). For example features such as blood and sample size of 50µl to 100µl, UV laser radiation, a (ToF) mass spectrometer are readily understood as standard practice or obvious variations available to a skilled addressee.

Continued on supplemental Sheet

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

Novelty and Inventive Step: claim 37

The invention of claim 37 is directed to a method of collecting a fluid sample at least capable of mass spectrometry analysis of multiple element content (of the sample). The method includes the application of a sample to an inert matrix having a low background element content, wherein the matrix is selected from the group consisting of aragonite, aluminium hydroxide, titania, glucose, Starch A, Starch B, glucodin, cellulose powder/granules, fibrous cellulose, hydroxyl butyl methyl cellulose, vegetable flour or mixtures thereof.

This method is clearly disclosed in citations (a), (b), and (e) and therefore not considered novel nor inventive. See for example in citation (a) the disclose of the matrix being impregnated with the typical reagents (as listed in column 7), a fluid sample taken, and passed through a diffuse reflectance spectrophotometer to determine glucose levels in blood, (as disclosed in columns 8 and 9).